IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 12-1298-UNA
	)	
IMPAX LABORATORIES, INC.,	)	
	)	
Defendant.	)	

DEFENDANT IMPAX LABORATORIES, INC.'S ANSWER AND COUNTERCLAIMS TO COMPLAINT

Defendant Impax Laboratories, Inc. ("Impax"), by and through its undersigned attorneys, hereby respond to the Complaint for Patent Infringement of Plaintiff Avanir Pharmaceuticals, Inc. ("Plaintiff") as follows.

Nature of Action

1. Paragraph 1 states legal conclusions and legal arguments to which no response is required. To the extent a response is required, Impax admits that this action purports to be for patent infringement under the patent laws of the United States, Title 35 United States Code. Impax further admits that it filed with the U.S. Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") to market a generic version of the Nuedexta® drug product before the expiration of U.S. Patent No. 8,227,484 ("the '484 patent").

The Parties

2. Impax lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2, and therefore denies the same.

3. Admitted.

4. Paragraph 4 states legal arguments and conclusions of law to which no response is required. To the extent a response is required, Impax admits that it is incorporated in the state of Delaware, that it maintains a registered agent for service of process in Delaware, and that it develops generic pharmaceutical products for sale in the United States. Impax denies the remaining allegations in Paragraph 4.

Jurisdiction and Venue

5. Paragraph 5 states conclusions of law for which no response is required. To the extent a response is required, Impax does not contest that this Court has subject matter jurisdiction over the instant case for the purposes of adjudicating Plaintiff's infringement claims under 35 U.S.C. § 271(e)(2)(A). Impax denies any remaining allegations in Paragraph 5.

6. Paragraph 6 states conclusions of law for which no response is required. To the extent a response is required, Impax does not contest that this Court has personal jurisdiction over it for the limited purpose of adjudicating the instant case. Impax denies any remaining allegations in Paragraph 6.

7. Paragraph 7 states conclusions of law for which no response is required. To the extent a response is required, Impax does not contest venue in this district. Impax denies any remaining allegations in Paragraph 7.

The Patent-in-Suit

8. Impax admits that Exhibit A to Plaintiff's Complaint purports to be a copy of the '484 patent. Impax further admits that the face of the '484 patent indicates that it was issued on July 24, 2012, that the title is listed as "Pharmaceutical Compositions Comprising Dextromethorphan and Quinidine for the Treatment of Neurological Disorders," and that the inventors listed are

Gerald Yakatan, James Berg, Laura Pope, and Richard Smith. Impax denies that the '484 patent is duly and lawfully issued. Impax denies any remaining allegations in Paragraph 8.

The NUEDEXTA® Drug Product

9. Impax admits that Avanir Pharmaceuticals, Inc. is identified by the FDA as the holder of approved New Drug Application ("NDA") No. 21-879 for dextromethorphan hydrobromide/quinidine sulfate capsules, which are sold under the trade name Nuedexta®. Impax further admits that the face of the '484 patent identifies Avanir Pharmaceuticals, Inc. as the assignee. The scope of the claims is a legal conclusion for which no response is required. Impax lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 9, and therefore denies the same.

10. Impax admits that the '484 patent is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), with respect to Nuedexta®. The remaining allegations contained in Paragraph 10 are conclusions of law for which no response is required.

Acts Giving Rise to this Suit

11. Impax admits that it filed Abbreviated New Drug Application ("ANDA") No. 203-061 seeking FDA approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of 20 mg dextromethorphan hydrobromide/10 mg quinidine sulfate capsules before the patents-in-suit expire. Impax denies the remaining allegations in Paragraph 11.

12. Impax admits that it provided a written certification to the FDA as required by Section 505 of the Federal Food Drug and Cosmetic Act asserting that the '484 patent is invalid, unenforceable, and/or will not be infringed by the product and/or activities described in ANDA No. 203-061. Impax denies the remaining allegations in Paragraph 12.

13. Impax admits that, no earlier than September 20, 2012, it sent written notice to Avanir Pharmaceuticals, Inc. ("Impax's Notice Letter") pursuant to 21 U.S.C. § 355G)(2)(A)(vii)(IV) that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the product and/or activities described in ANDA No. 203-061, and that Impax's Notice Letter speaks for itself. Impax denies the remaining allegations in Paragraph 13.

Count I: Alleged Infringement of the '484 Patent

14. Impax incorporates by reference and repeats its responses to Paragraphs 1-13, as if fully set forth herein.

15. Denied.

16. Paragraph 16 contains a conclusion of law for which no response is required. To the extent a response is required, Impax admits that a justiciable controversy exists between it and Plaintiff with regard to the '484 patent. Impax denies any remaining allegations in Paragraph 16.

17. Denied.

18. Denied.

19. Denied.

20. Denied.

21. Denied.

22. Denied.

PRAYER FOR RELIEF

Impax denies that Plaintiff is entitled to any of the relief that it seeks in the prayer for relief or any relief whatsoever.

AFFIRMATIVE DEFENSES

Without admission as to the burden of proof, burden of persuasion, or the truth of any allegation in Plaintiff's Complaint, Impax states the following defenses:

First Affirmative Defense

Each purported claim for relief in Plaintiff's Complaint is barred for failure to state a claim upon which relief may be granted.

Second Affirmative Defense

Plaintiff's claims for relief are barred for lack of subject matter jurisdiction insofar as they include claims for patent infringement under 271 U.S.C. §§ 271 (a), (b) and (c).

Third Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of the dextromethorphan hydrobromide/quinidine sulfate capsules that are the subject of ANDA No. 203-061 ("Impax's ANDA product") and Impax's activities have not infringed, do not infringe and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '484 patent.

Fourth Affirmative Defense

The claims of the '484 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, 112, 116, and/or for improper double patenting.

Fifth Affirmative Defense

Impax's actions with respect to its ANDA No. 203-061 and in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Affirmative Defense

By reason of the prior art and/or statements and representations made to the United States Patent and Trademark Office during the prosecution of the applications that led to the issuance of the '484 patent, the patent is so limited that no claim can be construed as covering any Impax activity or the Impax ANDA product.

Seventh Affirmative Defense

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

Eighth Affirmative Defense

Plaintiff's claims and requested relief are barred by the doctrines of estoppel, waiver, and/or laches.

Ninth Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Impax Laboratories, Inc. ("Impax"), for its Counterclaims against Plaintiff Avanir Pharmaceuticals, Inc. ("Plaintiff"), alleges as follows:

The Parties

1. Impax Laboratories, Inc. is a Delaware corporation with a principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

2. On information and belief, Avanir Pharmaceuticals, Inc. is a Delaware corporation with a principal place of business at 20 Enterprise, Suite 200, Aliso Viejo, California 92656.

Jurisdiction and Venue

3. These claims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

4. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. Plaintiff, by bringing this action in this District, has consented to and is subject to personal jurisdiction in this District.

6. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

7. There is an actual and justiciable controversy between the parties as to the infringement, validity and enforceability of the '484 patent.

Background

8. On information and belief, United States Patent No. 8,227,484 ("the '484 patent"), entitled "Pharmaceutical Compositions Comprising Dextromethorphan and Quinidine for the Treatment of Neurological Disorders," was issued on July 24, 2012.

9. On information and belief, Avanir Pharmaceuticals, Inc. is the assignee of the '484 patent. Further, on information and belief, Avanir Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 21-879 for dextromethorphan hydrobromide/quinidine sulfate capsules.

10. The '484 patent is listed in the Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with Nuedexta®, the drug for which Plaintiff submitted NDA No. 21-879.

11. On information and belief, Nuedexta® is the trade name under which Plaintiff sells and distributes dextromethorphan hydrobromide and quinidine sulfate capsules.

12. Impax has submitted Abbreviated New Drug Application ("ANDA") No. 203-061

(Impax's ANDA) to obtain FDA approval to engage in the commercial use, manufacture, sale, offer for sale or importation of dextromethorphan hydrobromide/quinidine sulfate capsules before the '484 patent expires.

13. Impax's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355 (G)(2)(A)(vii)(IV) that the '484 patent is invalid, unenforceable and/or will not be infringed by the commercial use, manufacture, sale, offer for sale or importation of the product described in Impax's ANDA or Impax's activities.

14. On October 8, 2012, Plaintiff filed this instant suit alleging infringement of the '484 patent.

First Count
Declaration of No Infringement of the '484 Patent

15. Impax incorporates by reference the allegations in Paragraphs 1-14 of its Counterclaims, as if fully set forth herein.

16. Plaintiff has asserted the '484 patent against Impax. Plaintiff alleges—and Impax denies—that the claims of the '484 patent cover Impax's ANDA product and/or activities. As a result, Impax has adverse legal interests from Plaintiff, and there is a substantial controversy between the parties concerning Impax's alleged infringement of the '484 patent that is of sufficient immediacy to create a present, genuine, and justiciable controversy and to warrant the exercise of the Court's declaratory judgment jurisdiction over this counterclaim.

17. The claims of the '484 patent do not, either literally or under the doctrine of equivalents, cover Impax's ANDA product. Thus, the manufacture, use, sale, offer for sale or importation of the dextromethorphan hydrobromide/quinidine sulfate capsules that are the subject of Impax's ANDA have not infringed, do not infringe, and will not infringe any valid or enforceable claim of the '484 patent. Further, Impax's filing of ANDA No. 203-061 has not

infringed, does not infringe, and will not infringe any valid and enforceable claim of the '484 patent.

18. Impax has not induced or contributed to, and does not and will not induce or contribute to, any infringement of any valid and enforceable claim of the '484 patent. Further, Impax is not liable for any act that could be construed as any form of infringement of any valid and enforceable claim of the '484 patent.

19. Impax is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Impax's ANDA product and Impax's activities have not infringed, do not infringe, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '484 patent.

Second Count
Declaration of Invalidity of the '484 Patent

20. Impax incorporates by reference the allegations in Paragraphs 1-19 of its Counterclaims, as if fully set forth herein.

21. The '484 patent and all of its claims are invalid for failure to comply with Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, 112, 116, and/or for improper double patenting.

22. A present, genuine, and justiciable controversy exists between Impax and Plaintiff regarding, *inter alia,* the validity of the claims of the '484 patent.

23. Impax has adverse legal interests from Plaintiff with respect to the '484 patent, and there is a substantial controversy between Impax and Plaintiff of sufficient immediacy and reality to warrant the exercise of the Court's declaratory judgment jurisdiction over this counterclaim.

24. Impax is entitled to a judicial declaration that the claims of the '484 patent are invalid.

Request for Relief

WHEREFORE, Impax requests judgment in its favor and against Plaintiff as follows:

(a) Dismissing Plaintiff's Complaint for Patent Infringement with prejudice and denying each request for relief made by Plaintiff;

(b) Declaring that the filing of Impax's ANDA has not infringed, does not infringe, and will not infringe (directly or indirectly) any valid or enforceable claim of the '484 patent;

(c) Declaring that the manufacture, use, offer to sell, sale, and/or importation of Impax's products that are the subject of Impax's ANDA, and Impax's activities, have not, do not, and will not infringe (directly or indirectly) any valid and enforceable claim of the '484 patent;

(d) Declaring all claims of the '484 patent invalid;

(e) Permanently enjoining Plaintiff, its respective directors, officers, agents, successors, assigns and all others acting on behalf of, or acting in concert or participation with, Plaintiff from asserting or otherwise seeking to enforce the '484 patent against Impax or anyone in privity with Impax;

(f) Declaring this case exceptional and awarding Impax its reasonable attorney's fees pursuant to 35 U.S.C. § 285;

(g) Awarding Impax its costs and expenses incurred by this action; and

(i) Awarding such other and further relief as this Court deems just and proper.

Date: October 10, 2012

PHILLIPS, GOLDMAN & SPENCE, P.A.

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